

MAY 28 2004

K041116

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## 510(k) Summary – Super QuickAnchor Plus

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**Submitter's Name and Address:**

DePuy Mitek  
a Johnson & Johnson company  
249 Vanderbilt Avenue  
Norwood, MA 02062

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**Contact Person**

Allyson Barford  
Regulatory Affairs Associate  
DePuy Mitek  
a Johnson & Johnson company  
249 Vanderbilt Avenue  
Norwood, MA 02062  
Telephone: 781-251-2794  
Facsimile: 781-278-9578  
e-mail: [abarford@dpyus.jnj.com](mailto:abarford@dpyus.jnj.com)

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**Name of Medical Device**

Device Regulation:  
Staple, Fixation, Bone  
(21 CFR 888.3030)  
Product code: MBI

Common/Usual Name:  
Staple, Fixation, Bone

Proprietary Name:  
Super QuickAnchor Plus

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**Device Classification**

Staple, Fixation, Bone devices have been classified as Class II, MBI according to 21 CFR 888.3030. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Staple, Fixation, Bone devices.

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**Indications for Use**

The Mitek Super QUICKANCHOR Anchor Plus is intended for fixation of USP size #2 through #5 suture to bone for the indications listed below.

Shoulder: Rotator cuff repair; capsular repair; biceps repair; deltoid repair.

Ankle: Achilles tendon repair/reconstruction.

Knee: Extra capsular repairs; Reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint

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capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

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**Device Description**

The Super QuickAnchor Plus is intended as an upgrade of the current Super QuickAnchor. The new system includes enhanced ergonomics, and improved visualization. The product will be offered with both Ethibond and Panacryl suture. The ergonomics are improved by allowing a single-handed operation. In addition, the visualization of the anchor is improved by increasing the length of the inserter shafts. The Super QuickAnchor is a metallic (6Al-4V ELI Titanium base and NiTi Titanium Alloy arcs) anchor and is used to assist in the reattachment of soft tissue to bone. The anchor is identical to the currently marketed Mitek SuperAnchor QuickAnchor (K930893).

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**Substantial Equivalence**

Based on the type of changes being made and the fact that the Super QuickAnchor Plus represents the same fundamental scientific technology as the existing SuperAnchor QuickAnchor; Mitek believe that Super QuickAnchor Plus is substantially equivalent to Mitek's existing SuperAnchor QuickAnchor (K980893).

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**Safety**

Biocompatibility studies have demonstrated the Super Anchor QuickAnchor Plus to be non-toxic, non-irritating, and non-cytotoxic.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 28 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Allyson Barford  
Regulatory Affairs Associate  
Depuy Mitek  
a Johnson & Johnson Company  
249 Vanderbilt Avenue  
Norwood, Massachusetts 02062

Re: K041116

Trade/Device Name: Super QuickAnchor Plus

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: JDR

Dated: April 5, 2004

Received: April 29, 2004

Dear Ms. Barford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

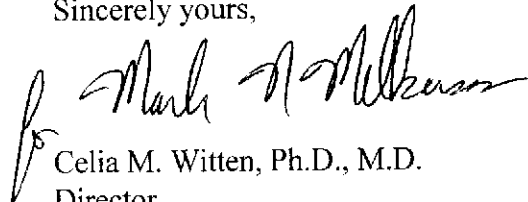
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K041116

Device Names:

Super QuickAnchor Plus

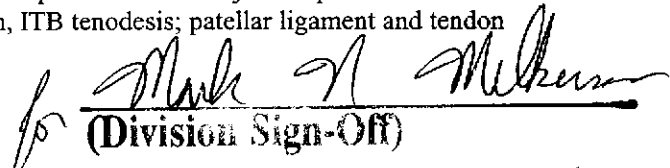
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(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K041116

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use \_\_\_\_\_

Special 510(k) Premarket Notification: Super QuickAnchor Plus  
DePuy Mitek

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